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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,911	09/24/2003	Elly Nedivi	01997/547002	6520
21559	7590	11/14/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			WEGERT, SANDRA L	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 11/14/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/670,911	<b>Applicant(s)</b> NEDIVI ET AL.	
	<b>Examiner</b> Sandra Wegert	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 21-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                  |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                             | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/23/05</u> . | 6) <input type="checkbox"/> Other: _____                                                |

DETAILED ACTION

***Status of Application, Amendments, and/or Claims***

The Information Disclosure Statement sent 23 May 2005 has been entered into the record. Applicants' election of Invention III (Claims 15-20), without traverse, in the Paper of 9 August 2006 is acknowledged.

Claims 1-14 and 21-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Claims 15-20 are under examination in the instant Application.

**Claim Objections/Rejections**

***Claim Rejections-Prior Art***

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-20 are rejected under 35 U.S.C. 102(b) as being unpatentable over Zhou, et al, (5 April 2000, Accession No. AAF62371). Zhou, et al disclose a polypeptide that, within residues 28-114, bears 100% homology to SEQ ID NO: 1 of the instant Application (see

Art Unit: 1647

enclosed alignment). The protein of the instant application is 87 amino acids in length. The polypeptide disclosed in Zhou, et al, comprises the entire sequence of SEQ ID NO: 1 plus additional residues at either end. This reference thus anticipates Claims 15-20 in their entirety, since Claim 19 recites "comprising" SEQ ID NO: 1.

Claims 15-20 are also rejected under 35 U.S.C. 102(b) as being unpatentable over Naeve, et al (1997, Proc. Natl. Acad. Sci., 94: 2648-2653). Naeve, et al disclose a polypeptide that bears 100% homology to SEQ ID NO: 1 of the instant Application at residues 28-114. In other words SEQ ID NO: 1 corresponds to the disclosed Naeve, et al peptide at residues 28-114. In the publication, they refer to the polypeptide as "neuritin," and Accession No. U88950, but it appears to be non-soluble CPG. The authors measured neuronal arborization caused by neuritin in hippocampal neurons, among other developmental experiments. The publication did not discuss removal of the neuritin/CPG signal sequence or the GPI sequence, as recited in claims 16 and 17, but the reference still anticipates Claims 15-20 in their entirety, since claim 19 recites "comprising" SEQ ID NO: 1 and all claims encompass CPG/neuritin.

Claims 15-20 are also rejected under 35 U.S.C. 102(b) as being unpatentable over Nedivi, et al (1998, Science 281: 1863-1866). Nedivi, et al, disclose a polypeptide that bears 100% homology to SEQ ID NO: 1 of the instant Application at residues 28-114. In other words SEQ ID NO: 1 corresponds to the disclosed Nedivi, et al peptide at residues 28-114. In the publication, the authors refer to the polypeptide as "CPG15." The authors measured dendritic elaborization caused by CPG15 in the developing *Xenopus* tectum, and discovered that CPG15 is also involved in cell-to-cell communication of developing neurons. The publication did not discuss removal of the CPG15 signal sequence or the GPI-linkage sequence, as recited in claims

Art Unit: 1647

16 and 17, but the Nedivi reference still anticipates Claims 15-20 in their entirety, since claim 19 recites a composition "comprising" SEQ ID NO: 1, and all claims encompass CPG15.

***Claim Rejections-35 USC § 112, first paragraph –Enablement and Written Description.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 15-18 and 20 are single means claims, i.e., where a means recitation does not appear in combination with another recited element of means, the claims are subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

***Written Description.***

Claims 15-18 and 20 are also rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to

Art Unit: 1647

reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 15-18 and 20 are directed to a composition of matter comprising a polypeptide that has s-CPG15 activity. Further claim limitations are presented to polypeptides comprising SEQ ID NO: 1, and s-CPG15 comprising post-translational modifications.

The specification teaches a polypeptide (SEQ ID NO: 1) and describes it as a member of the family of "candidate plasticity [genes]" involved in cell differentiation, growth, and apoptosis, among other functions (see Lee & Nedivi, 2002, J. Neurosci., 22(5): 1807-1815, submitted by Applicants, 23 May 2005). The Specification also describes experiments in which s-CPG15 was used *in vitro* and *in vivo* to inhibit apoptosis in developing or stressed neurons. However, the specification does not teach functional or structural characteristics of all peptides "having s-CPG15 biological activity." The description of one polypeptide (SEQ ID NO: 1) that does have s-CPG15 activity is not adequate written description of an entire genus of functionally equivalent polypeptides.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides that have s-CPG15 activity, and

Art Unit: 1647

therefore, would not know how to make or use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The polypeptide *itself* is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the purified polypeptide of SEQ ID NO: 1, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

### ***Claim rejections- indefiniteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1647

Claims 15-20 provide for a composition of matter comprising a polypeptide having s-CPG activity. However, the claims do not set forth examples of such activity nor any further requirements of the composition of matter or polypeptide. Thus, it is unclear what is meant by the recited biological activity. A claim is indefinite where it merely recites an activity for a polypeptide, without further delineating the identifying characteristics of that polypeptide.

Claims 15-20 are also vague and indefinite because these claims recite the term "s-CPG15." This is an acronym and is arbitrary. Proteins can have various names, or the names can change. In the interest of clarity, acronyms should be spelled out in each independent claim.

Claim 18 is also vague and indefinite because it recites a CPG15 protein bound to a cell membrane and the CPG15 protein released from the cell. It would seem that these two requirements ("bound" and "released") are in conflict. Replacing the word "and" with the word "or" would be remedial.

## **Conclusion**

No claims are allowed.

## **Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.




Art Unit: 1647

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

7 November 2006

  
EILEEN B. O'HARA  
PRIMARY EXAMINER